

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

<b>IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>  <b>THIS DOCUMENT RELATES TO:</b>  <b>ALL WAVE 2 PLAINTIFFS LISTED IN EXHIBIT 1 TO PLAINTIFFS' MOTION<sup>1</sup></b>	<b>Master File No. 2:12-MD-02327 MDL 2327</b>  <b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>
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**RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE  
OPINIONS AND TESTIMONY OF JANET E. TOMEZSKO, M.D.**

Janet E. Tomezsko, M.D. is an experienced urogynecologist and board-certified pelvic-floor surgeon who has performed thousands of pelvic and vaginal polypropylene mesh implant surgeries, including those utilizing Ethicon's TVT products. Dr. Tomezsko is well-versed in the use of mesh products during pelvic-floor surgery, has educated residents and fellows in their use, and has, throughout her career, kept abreast of issues in her field by review and study of the relevant literature.

Despite this extensive career, Plaintiffs seek to exclude all or some of Dr. Tomezsko's opinions based on vague or nonspecific arguments where they claim Dr. Tomezsko:

- Did not account for contrary literature about chronic inflammation—yet they cite to no literature that Dr. Tomezsko failed to consider;
- Relies on observations from her practice to give an opinion about the adequacy of the TVT IFU—when she does not;

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<sup>1</sup> The only active case on Plaintiffs' Exhibit 1 is the case involving Plaintiff Ramona Phillips, Case No. 2:12-cv-02143.

- Gives ambiguous and unsupported “opinions” about the removal of TVT devices—when the testimony excerpted is neither;
- Cannot rely on the Cochrane Review because the meta-analysis includes devices not limited to the TVT—yet fails to acknowledge that the “vast majority” of the data analyzed in the Cochrane Review involves the TVT; and
- Should be limited to the opinions expressed in her deposition—but fail to cite to any authority or assert any argument as to why. And even if inconsistency between Dr. Tomezsko’s report and deposition is the unstated reason, this is a matter for cross-examination, not a basis for exclusion.

Plaintiffs’ challenges to Dr. Tomezsko’s opinions are meritless under Rule 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Their motion should be denied.

### **ARGUMENTS AND AUTHORITIES**

#### **I. Dr. Tomezsko’s chronic inflammation opinion is based on her review of the medical literature—a well-accepted methodology under *Daubert*.**

A physician’s “knowledge, experience, and review of scientific literature provide sufficiently reliable bases for his opinions under *Daubert*.” *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 714 (S.D.W. Va. 2014). This Court in particular has made clear that a physician can draw upon her clinical experience and review of relevant literature to give an opinion on the safety and efficacy of polypropylene mesh products. *See Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 585 (S.D.W. Va. 2014) (finding that a urologist with extensive clinical experience and relying on peer-reviewed literature could opine on the safety and efficacy of polypropylene mesh products).

Dr. Tomezsko used this scientifically reliable methodology here. Her report contains multiple references to the scientific literature (*see generally* Ex. A to Pls.’ Mot. (Dkt. 2435-2), Tomezsko Report) and she relied on that literature along with her clinical experience in forming her opinions. But, relying on isolated excerpts of Dr. Tomezsko’s deposition testimony and then

taking them out of context, Plaintiffs argue that the literature relied upon is “selective” and that Dr. Tomezsko “ignore[d] scientific scholarship refuting them.” *See* Pls.’ Mem. (Dkt. 2440) at 4.

Plaintiffs’ argument fails for two reasons. First, the testimony Plaintiffs rely upon does not support their argument. Plaintiffs’ counsel asked, in general terms, whether Dr. Tomezsko was aware of literature that “suggests” that polypropylene mesh used in the TVT can result in chronic inflammation. *Id.* at 5; *see also* Ex. 1, Tomezsko 6/27/16 Dep. Tr. 49:21-50:1, 50:8-12. Dr. Tomezsko responded that she looks “at the literature for what it proves, not what it suggests.” *Id.* at 50:2-3. Even though Dr. Tomezsko asked counsel to identify specifically the literature counsel was referring to (*id.* at 50:16-18), which counsel did not do, Dr. Tomezsko’s explanation that she looks to literature for what it proves, not what it suggests, is sufficient explanation. *Cf. Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D.W. Va. Sept. 29, 2014), and *Wilkerson v. Boston Scientific Corp.*, No. 2:13-CV-04505, 2015 WL 2087048 (S.D.W. Va. May 5, 2015). Unlike both *Sanchez* and *Wilkerson* where Dr. Margolis was asked about specific literature,<sup>2</sup> Plaintiffs’ counsel did not, and still has not, identified any specific literature that allegedly is contrary to Dr. Tomezsko’s opinions. Rather, Dr. Tomezsko explained, in the same general terms she was asked, that she looks to literature for what it proves, not what it suggests.

Second, even if she believes “there is some [literature] out there” that counsel failed to specifically question, this is no concession that she failed to account for contrary literature. Viewing her testimony in full on this issue and in the context it was given, shows that she explained why she rejected this nonspecific contrary literature.

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<sup>2</sup> *See Sanchez*, 2014 WL 4851989, at \*12 (failing to explain why he rejected the *Nilsson* study); *Wilkerson*, 2015 WL 2087048, at \*10 (reforming his opinion to now explain the basis for rejecting the *Nilsson* study)

Q. Okay. Doctor, if there is literature out there that would show that there is a chronic inflammation associated with the implantation of the TVT Retropubic device, is it fair to say you disagree with that literature?

...

A. I would disagree with that literature based on the multiple meta-analysis, long-term studies showing the low rate of complications that we actually see such as erosions or pain. So that's what matters.

Ex. 1, Tomezsko 6/27/16 Dep. Tr. 50:20-51:7.

Contrary to Plaintiffs' argument then that Dr. Tomezsko made "no attempt" to review contrary literature on chronic inflammation (Pls.' Mem. (Dkt. 2440) at 5), she did. And she sufficiently explained her reasons for rejecting it, just as Dr. Margolis did in his reformed opinions in *Wilkerson*. See *Wilkerson*, 2015 WL 2087048, at \*10. Plaintiffs' contrary-literature argument is meritless and should be rejected.

## **II. Dr. Tomezsko is qualified to give the IFU opinion Plaintiffs challenge.**

Plaintiffs claim, without support, that Dr. Tomezsko offers opinions about the adequacy of the TVT IFU on the same basis as did the expert in *Sederholm v. Boston Scientific Corp.*, No. 2:13-cv-12510, 2016 WL 3282587 (S.D.W. Va. June 14, 2016)—“based solely on the risks [she] observed in [her] practice.” Pls.' Mem. (Dkt. 2440) at 6. Yet, Plaintiffs point to no warnings opinions where Dr. Tomezsko has done so, nor did she. On the contrary, the opinion that Plaintiffs challenge—*i.e.*, that the TVT IFU “presents the risks of the device which would not otherwise be known by pelvic surgeons” (*id.*)—is one grounded in the scientific method, the law, and within her expertise.

It is well-established that a medical device manufacturer has no duty to warn of risks within the common knowledge of a physician, the learned intermediary.<sup>3</sup> *See Phelps v. Sherwood Med. Indus.*, 836 F.2d 296, 303 (7th Cir. 1987). Dr. Tomezsko testified repeatedly of the risks that are well known to pelvic-floor surgeons and how physicians gain this information beginning in medical school and, progressing through the physician's career, from the physician's clinical experience, attending professional meetings, and staying current with research and review of the literature. Ex. 1, Tomezsko 6/27/16 Dep. Tr. 131:21-132:9, 132:24-133:7, 137:23-138:9, 147:17-149:19; *see also* Ex. A to Pls.' Mot. (Dkt. 2435-2), Tomezsko Report at 23-24. Her opinions on this issue are consistent with the legal principle that there is no duty to warn of risks commonly known to surgeons who use the device. 21 C.F.R. § 801.109(c) (providing that information may be omitted from labeling for prescription device "if, but only if, the article is a device for which directions, hazards, warnings and other information are commonly known to practitioners licensed by law to use the device.").

Dr. Tomezsko is qualified to offer these opinions. She is a fellowship-trained pelvic-floor surgeon who is board-certified in both obstetrics and gynecology and female pelvic medicine and reconstructive surgery. Ex. 1, Tomezsko 6/27/16 Dep. Tr. 19:18-19, 21:8-14, 22:1-8. She is a specialist in female pelvic medicine and reconstructive surgery (*id.* at 21:4-7), conducts research in this area of medicine (*id.* at 22:11-21), is involved in clinical studies (*id.* at 23:5-24:3), and trains fellows and residents (*id.* at 114:7-8). Over her career, she has implanted between 1,000 and 1,500 TVT devices, and removed around five or so. *Id.* at 27:6-9, 29:24-30:3, 176:8-177:5.

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<sup>3</sup> The only remaining case to which Plaintiffs' motion applies—i.e., Plaintiff Ramona Phillips—is governed by Indiana law. Under that law, a medical device manufacturer's duty runs to the physician under the learned-intermediary doctrine. *Ortho Pharm. Corp. v. Chapman*, 388 N.E.2d 541, 549 (Ind. Ct. App. 1979); *see also Minisan v. Danek Med., Inc.*, 79 F. Supp. 2d 970, 978 (N.D. Ind. 1999).

As an experienced pelvic-floor surgeon, she is well-versed in the risks that are known by pelvic floor surgeons and qualified to give opinions about those risks. She need not be familiar with FDA rules or regulations to give this testimony. *Winebarger v. Boston Scientific Corp.*, No. 2:13-cv-28892, 2015 WL 1887222, at \*6-7, 15 (S.D.W. Va. April 24, 2016); *see also Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 703-04, 719 (S.D.W. Va. 2014) (finding Drs. Rosenzweig and Blaivas adequately experienced physicians to testify to risks of surgery and whether the risks were addressed in the IFU despite lack of expertise in FDA regulations or standards governing device warnings); *Trevino v. Boston Scientific Corp.*, 2:13-cv-01617, 2016 WL 2939521, at \*13-14 (S.D.W. Va. May 19, 2016) (finding Dr. Shull qualified to testify “on the completeness and accuracy of the [mesh product’s] warnings from a clinical perspective”). Indeed, a physician is qualified to make a comparison between “the risks [the physician] perceives that the [device] poses to patients” and whether the labels “convey these risks to physicians.” *Id.* (finding Dr. Shull qualified to give opinions on product labeling based on his clinical experience because his testimony did not touch on regulatory issues).

In addition to her training, clinical experience, and general knowledge as a pelvic-floor surgeon, Dr. Tomezsko draws on her knowledge of complications discussed in the medical literature, statements of leading medical societies, and core curriculum materials in formulating her opinions about commonly known risks. Ex. 1, Tomezsko 6/27/16 Dep. Tr. 147:14-149:20, 164:11-175:15 (discussing various scientific literature relied upon in forming her opinions). Based on this support, Dr. Tomezsko is qualified to form the opinion that Plaintiffs challenge—*i.e.*, that the TVT IFU “presents the risks of the device which would not otherwise be known by pelvic surgeons.” *See* Pls.’ Mem. (Dkt. 2440) at 6.

And she does so, not based on the risks observed in her practice as Plaintiffs argue, but on her knowledge as a pelvic-floor surgeon, her experience, and her review of the literature. Plaintiffs' reliance then on *Sederholm* is misplaced. Unlike the physician expert in that case, Dr. Tomezsko is not offering an opinion that the TVT IFU is adequate because it included risks she has observed in her own practice. *Compare Sederholm*, 2016 WL 3282587 at \*13 with Ex. A to Pls.' Mot. (Dkt. 2435-2), Tomezsko Report at 24. While a single physician's experience may not be sufficient, it is scientifically sound methodology to rely upon a large pool of scientific literature and studies, combined with the clinical experience and evaluation of many physicians and medical organizations, to support a conclusion that the IFU presents the risks that would not otherwise be known to pelvic surgeons, as Dr. Tomezsko does here. Any disagreement Plaintiffs may have with Dr. Tomezsko's conclusion goes to weight, not admissibility.

**III. Dr. Tomezsko's statements about removal of the TVT are neither ambiguous nor Dr. Tomezsko's *ipse dixit*.**

It is hard to discern the point Plaintiffs are trying to make with their "removal" argument. On one hand, it appears they take issue with Dr. Tomezsko's unwillingness to divulge what she perceives as confidential information and that testimony to this effect is ambiguous (*see* Pls.' Mem. (Dkt. 2440) at 6); on the other, it appears they take issue with her statement that removals are "rare" and that this testimony is *ipse dixit* (*id.* at 6-7). Either way, her "removal" testimony is neither and should be rejected for two reasons.

First, it is unclear of the significance of the testimony excerpted on page six of Plaintiffs' memorandum. Dr. Tomezsko is merely agreeing with Plaintiffs' counsel that removing the TVT entirely would require aggressive dissection and that there is no guarantee it can be done. Ex. 1, Tomezsko 6/27/16 Dep. Tr. 64:8-17. The excerpted testimony has nothing to do with Dr. Tomezsko's testimony about how "rare" it may be to remove the TVT entirely. Even if this

testimony can be “interpreted in two distinct ways” as Plaintiffs claim (Pls.’ Mem. (Dkt 2440) at 6)—and it cannot—this would be a matter for cross examination, not exclusion. Plaintiffs provide no authority to the contrary. Plaintiffs’ argument can be rejected outright on this basis alone.

Second, Dr. Tomezsko’s “removal” statements are based on her experience as a pelvic-floor surgeon and her interactions with other surgeons. She is relaying personal knowledge of what she has observed in practice. Ex. 1, Tomezsko 6/27/16 Dep. Tr. 62:14-64:7 (testifying about her knowledge of physicians who have removed the entire TVT device, which she gained from “patient cases”). This is not a *Daubert* issue.

#### **IV. Relying on the Cochrane Review is scientifically sound.**

Plaintiffs take issue with Dr. Tomezsko’s reliance on the 2015 Cochrane Review because it includes data about other devices besides the TVT. *See* Pls.’ Mem. (Dkt. 2440) at 7. Plaintiffs’ argument should be rejected for two reasons.

First, Dr. Tomezsko acknowledged that, while the Cochrane Review meta-analysis includes “various midurethral slings,” it is “heavily weighted upon the TVT data”; indeed, “the vast majority of the data that’s used is the TVT Retropubic.” Ex. 1, Tomezsko 6/27/16 Dep. Tr. 123:14-21. Plaintiffs’ attempt to characterize the 2015 Cochrane Review as literature that cannot support Dr. Tomezsko’s opinions is wrong. The Cochrane Review contains important information about the TVT upon which Dr. Tomezsko can reliably rely in formulating her opinions.

Second, Plaintiffs’ argument, in truth, takes issue with Dr. Tomezsko’s interpretation of the 2015 Cochrane Review, which is not a basis to exclude her opinions based on that literature; instead, it is a matter for cross-examination. *Tyree*, 54 F. Supp. 3d at 552 (“As the gatekeeper of expert testimony, [the Court] need not concern [it]self with the ‘correctness of the expert’s

conclusions’ and should instead focus on the ‘soundness of his methodology.’” (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995))). Indeed, even if the medical literature is “not seamlessly align[ed]” with an expert’s interpretation of a study, his methodology is not rendered unreliable as long as his interpretation is plausible. *Hovey v. Cook Inc.*, No. 2:13-cv-18900, 2015 WL 1405565, at \*5 (S.D.W. Va. Mar. 26, 2015); *see also United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (“The court need not determine that the proffered expert testimony is irrefutable or certainly correct.”); *Wise v. C.R. Bard, Inc.*, No. 2:12-cv-01378, 2015 WL 521202, at \*21 (S.D.W. Va. Feb. 7, 2015) (“The plaintiffs, instead, focus their arguments on why Dr. Clark’s ultimate conclusion—that degradation does not occur—is wrong according to other sources. However, under *Daubert*, the court is not to decide whether an opinion is scientifically correct; it is to evaluate the method a proffered expert uses in reaching that opinion.”).

Because Plaintiffs’ challenge here essentially goes to Dr. Tomezsko’s conclusions—not her methodology—their arguments fall outside the scope of a *Daubert* analysis and should be rejected.

**V. Dr. Tomezsko’s opinions are not limited to those she expressed in her deposition, but include those stated in her report.**

Plaintiffs’ last challenge is equally specious. Without analysis of any kind, Plaintiffs merely point to four statements that Dr. Tomezsko made during deposition and conclusorily state that Dr. Tomezsko’s opinions at trial should be limited to this testimony. *See* Pls.’ Mem. (Dkt. 2440) at 8. Plaintiffs cite to no legal authority of any kind to support this vague “argument,” nor can they. Indeed, if this were true, there would be no need to exchange expert reports and the opinions of experts never deposed would be inadmissible at trial.

But this is not the law, nor should it be. Experts in this litigation are deposed under strict time limitations. The opinions expressed by the various experts are expounded upon in their reports, not depositions. It would be unfair, and contrary to the rules of civil procedures and evidence to limit an expert's opinions to those expressed in deposition. Indeed, nothing in Rules 26, 702, or 703 support such a position.

Even to the extent that Plaintiffs' "argument" could be construed as alleging that Dr. Tomezsko's opinions expressed at deposition were inconsistent with those expressed in her report—and nothing in Plaintiffs' brief says as much—any discrepancies between an expert's report and testimony in deposition is a matter for cross-examination, not a basis for exclusion. *Eghnayem*, 57 F. Supp. 3d at 678.

Plaintiffs simply have no legal basis to claim that Dr. Tomezsko's opinions should be limited to those expressed at her deposition. This extreme position should be rejected.

### **CONCLUSION**

For the foregoing reasons, Ethicon respectfully asks this Court to deny Plaintiffs' motion.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I certify that on August 8, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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